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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,863	02/08/2000	FREDERIC DONIE	BMID9974US	7240

7590

01/28/2004

BRINKS HOFFER GILSON & LIONE  
P. O. BOX 10395  
CHICAGO, IL 60610

EXAMINER

LI, BAO Q

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/423,863

Applicant(s)

DONIE ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 65-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 65-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 65-87 are pending.

#### **RCE**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), paper No. 35, was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/2003 has been entered. The Action on RCE follows:

#### ***Response to Amendment***

This is a response to the amendment, paper No. 36, filed 06/23/01. Claims 1-64 have been canceled. New claims 65-87 are added. Claims 65-87 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 65-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 65-67, 75, 77, 78, 79, and 82-85 are vague and indefinite for using an open language "including" and "comprising" in the claims, which fail to define the metes and bounds of precise structures of claimed antigen epitopes.
4. MPEP 112.03 cites:

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5. The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”)

6. M.P.E.P 2006 also cites:

7. Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (“During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.”).

8. M.P. E.P. cites:

9. The inquiry during examination is patentability of the invention as applicant regards it. If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. 112, second paragraph. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). If a rejection is based on 35 U.S.C. 112, second paragraph, the examiner should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention. *Ex parte Ionescu*, 222 USPQ 537, 539 (Bd. App. 1984).

10. In the instant case, although the specification discloses several epitope regions I and II sequences listed on Table I–III, the limitation of the limitations appearing in the specification but not recited in the claim are not read into the claims. Moreover, the claims as drafted is directed to an epitopes located in the regions I and II as shown in Table I and II, rather than it is the whole regions designated as SEQ ID NO: 1-34 listed in Table I-III. Applicants are therefore, suggested to point out what the precise sequence structure of claimed antigen epitopes are.

11. Claims 65, 77, 82, 83, are also vague and indefinite in that the metes and bounds of the second epitope are not defined. For the same notion that Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55,

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44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. Applicants are suggested to point out what the precise structure(s) of the claimed second epitope(s) is in the claims.

12. Claims 66, 67, 78, 79, 84 and 85 are confusing and unclear in that the claimed epitopes sequences of SEQ ID NO: 32-35 and SEQ ID NOS: 37 and 38 do not meet the structural limitation or requirement of their independent claims 65, 77 and 83. The base claims 65, 77 and 83 require that a first antigen from the epitope region II of gp41 of HIV subtype D isolate in the region of amino acid residues of 518-533 as disclosed in Table I, the claimed sequences of antigen epitopes of SEQ ID NO: 29, 30, 31, 35, 36 and 39 are the sequences degenerated from that region. However, the SEQ ID NOS: 32-34 and 37-38 are not the sequences in that regions. It is unclear and confused how the claimed sequences of SEQ ID Nos: 32-3 and 37-38 can be the epitope II of subtype D within that claimed region because they are not the sequence of antigen gp41 epitope II of HIV subtype D in that region as disclosed in the Table I of specification.

13. The above rejections affect the dependent claims 69-73, 76, 86 and 87.

#### ***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 77, 79 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Formoso et al. (WO 90/07119A1).

16. Formoso et al. disclose an immunospecific reagent and a method for using the reagent for detecting HIV-1 infection, wherein the immunogenic reagent comprises at least one synthetic peptide having the immunoreactive specificity characteristic of the gp41 protein of HIV-1 conjugated through its C-terminus to a carrier protein, wherein the peptides 5S60 and 5S67 are peptides comprising the first epitope region II of an HIV-1 subtype D isolate in the region of amino acid residues 518-533. The peptide of 2S04, AB14, 3S36, 2S06, 28-7 and 2S09 comprises more than 7-10 amino acid residues of gp41 epitope II of different subtype isolate of HIV group

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M, such as 2S06 and 2S07 comprise 14 or 15 identical amino acid residues of subtype A, B, C, E and F of HIV group M gp41 region II. (See claims 2 and 11). Formoso et al. teach that the immunogenic reagent comprises at least one of these synthetic peptides. Therefore, it includes the combination of peptide 5S60 or 5S70, which comprises a first epitope of the epitope region II of gp41 of HIV subtype D, with peptide sequence including 2S04, AB14, 3S36, 2S06, 28-7 and 2S09, which does contain more than 7 amino acid residues of other subtype of a first epitope of the epitope region II of gp41 of HIV.

17. Because the rejected claims use an open language “comprising”, which only indicates that an antigen composition comprises an epitope that is located in the region II rather than precisely it is the full-length sequence of region II as disclosed in Table I of the specification. Hence the claimed invention is anticipated by the cited reference. Hence the claimed invention is anticipated by the cited reference. Hence the claimed invention is anticipated by the cited reference.

***Claim Rejections - 35 USC § 102***

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 77, 79 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Oldstone et al. (WP 89/01494A1).

20. Oldstone et al. disclose an immunospecific composition and a method of using the composition for detecting HIV-1 infection comprises at least two peptides from HIV-1 gp41 epitope II region. The first peptide antigen is sequence LGIWGCSGKHIC, which contains the epitope from the region II of HIV-1 subtype D gp41 and the second one is LGL(I)WGCSGKLIIC of gp41 epitope II from different subtype of HIV group M, such as A, E or F isolates (See claims 1-17). Because the rejected claims use an open language “comprising”, which only indicates that an antigen composition comprises an epitope that is located in the region II rather than precisely

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it is the full-length sequence of region II as disclosed in Table I of the specification. Hence the claimed invention is anticipated by the cited reference.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

January 21, 2004

  
JAMES HOUSEL 1/24/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600